Remarks

Initially, Applicants and their representative would like to thank Examiner Kumar for the time and courtesy extended to the undersigned in a personal interview Wednesday, October 18, 2006. During the interview, differences between the claimed implantable tissues and the tissues of the cited references were discussed as summarized below. In addition, amendments of the withdrawn claims were discussed that could result in the rejoinder of the withdrawn claims upon allowance of independent claim 20. The Examiner stated that further consideration of the rejections would be accorded upon review of the arguments presented herewith.

Claims 20, 21, 23, 24, 28-39 and 47 are currently pending in the application, including independent claims 20 and 30 and withdrawn claims 30-39 and 47. For instance, independent claim 20 is directed to an implantable fixed tissue comprising cross-linked elastin. More specifically, the elastin of the implantable fixed tissue is cross-linked with a phenolic tannin cross-linking agent. Accordingly, the implantable fixed tissue includes a residue of the phenolic tannin cross-linking agent.

In the Office Action, claims 22 and 25-27 were rejected as being indefinite. With no comment as to the appropriateness of the rejection, and for purposes of forwarding prosecution of the application, claims 22 and 25-27 have been cancelled.

In the Office Action, claims 20-21, 23-24, and 28 were rejected under 35 U.S.C. §102(e) as anticipated by, or, in the alternative under 35 U.S.C. §103(a) as obvious over Adkisson (U.S. Patent No. 6,645,764).

Applicants respectfully submit that the claims patentably define over the cited reference for at least the reason that Adkisson fails to disclose or suggest certain limitations of the claims. For example, Adkisson fails to disclose or suggest an implantable fixed tissue including cross-linked elastin and a residue of a phenolic tannin cross-linking agent.

Adkisson describes neocartilage formations useful as implants and replacement tissue. Adkisson also describes treatment of the formations for histological and biochemical assessment of the formed tissues. Treatment methods employed in evaluation of the tissues include fixing of the tissues with glutaraldehyde, post-fixing

with osmium-tetroxide, and staining with tannic acid and uranyl acetate (col. 6, ll. 1-4). However, the *implantable* neocartilage formations of Adkisson are not the same as the tissue that has been treated for histological evaluation.

For instance, Example 4 of the patent (col. 18, ll. 5-59) describes the production of neocartilage. Neocartilage was grown to day 30 and then following harvest was fixed, stained, and extracted for histological evaluation. The composition of this analyzed neocartilage is shown in Table III of the example. According to Table III, the neocartilage was primarily type II collagen, but also included type IX collagen, type XI collagen, and the proteoglycan aggrecan. Significantly, the compositional analysis of the neocartilage shown in Table III does not include any elastin. In addition, in Example 2 of Adkisson, biochemical assessment of the neocartilage formation failed to identify elastic fibers in the formed tissue (see, e.g., column 16, ll. 27-30). Thus, there is no teaching or suggestion in Adkisson of an implantable tissue including cross-linked elastin, as is found in the claims.

Moreover, Example 4 of Adkisson also describes the implantation of sterile neocartilage formed according processes described in the patent. There is no suggestion, however, that the sterile neocartilage that was implanted, was treated in a like manner as the neocartilage that was harvested, fixed, stained, and extracted for the compositional assay. The patent describes utilization of tannic acid as a stain for preparation of materials for histological purposes. The *sterile* neocartilage that was implanted in the animals, however, was not treated with tannic acid as were the analyzed samples. As such, the sterile neocartilage implants do not include the residue of a phenolic tannin cross-linking agent, as is found in the implantable tissues of the pending claims.

Accordingly, Applicants maintain that Adkisson does not disclose or suggest implantable fixed tissue including cross-linked elastin and the residue of a phenolic tannin cross-linking agent, as is found in the pending claims. As such, Applicants maintain that the pending claims patentably define over Adkisson.

In the Office Action, claims 20-24 and 28-29 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C.§103(a) as obvious over Nimmi, et al. (U.S. Patent No. 5,374,539).

Nimmi, et al. is directed to a method for preparing a purified collagen network. The method includes subjecting tissue to proteolytic enzymes in the presence of salt to remove not only the non-helical extensions at either end of a collagen molecule, but also cellular proteins, interfibrillar proteins, glycoproteins, residual serum proteins, and other extraneous material leaving behind the helical region of collagen (col. 3, l. 56 – col. 4, l. 10). Specifically, Nimmi, et al. describes methods of preparing purified collagen (the section beginning at col. 4, l. 55) and methods of preparing purified collagen scaffolds (the section beginning at col. 5, l. 16) through the enzymatic digestion of non-collagenous remnants of the starting materials (see, e.g., claim 1). Hence, as Nimmi, et al. teaches the removal of non-collagenous materials during formation of purified collagen, the patent fails to disclose or suggest an implantable tissue including cross-linked elastin, as is found in the implantable tissues of the pending claims. Accordingly, Applicants respectfully submit that Nimmi, et al. fails to disclose or suggest features of the pending claims and request allowance of the claims.

As a final matter, Applicants respectfully request rejoinder of withdrawn claims 30-39 and 47 to the pending application. The claims are related as subcombination/combination claims. Such claims require two-way distinctness for maintenance of a restriction requirement. Specifically, the inventions are distinct if it can be shown that a combination as claimed (A) does not require the particulars of the subcombination as claimed for patentability and (B) the subcombination can be shown to have utility either by itself or in another materially different combination (MPEP §806.05(c)). In the present instance, Applicants submit that the combination as claimed in independent claim 30 requires the implantable fixed tissue as claimed in the subcombination of independent claim 20. Accordingly, the two-way distinctness requirement has not been met, and Applicants request rejoinder of the claims.

It is believed that the present application is in complete condition for allowance

and favorable action is therefore requested. Examiner Kumar is invited and encouraged to telephone the undersigned at her convenience should there be any questions with regard to this application.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,
DORITY & MANNING, P.A.

11/14/06 BY: _____

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